510(k) Premarket Notification

SONOACE R7 Diagnostic Ultrasound System

# 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

### 1. Submitter's Information: 21 CFR 807.92(a)(1)

SAMSUNGMEDISON CO., LTD. 42, Teheran-ro 108-gil, Gangnam-gu, Seoul, Korea

#### **Contact Person:**

Kyeong-Mi, Park

Regulatory Affairs Manager

Telephone:

82.2.2194.1373

Facsimile:

82.2.556.3974

Data Prepared: September 9, 2013

#### 2. Name of the device:

#### Common/Usual Name:

Diagnostic Ultrasound System and Accessories

# Proprietary Name:

SONOACE R7 Diagnostic Ultrasound System

Classification Names:	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	ΙΥΝ
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

## 3. Identification of the predicate or legally marketed device:

- SONOACE R7 Diagnostic Ultrasound System(K112646)
- UGEO HM70A Diagnostic Ultrasound System (K130803)
- ACCUVIX A30 Diagnostic Ultrasound System(K112339)
- EKO 7 Diagnostic Ultrasound System (K101455)
- UGEO H60 Diagnostic Ultrasound System (K122583)
- UGEO PT60A Diagnostic Ultrasound System (K132228)
- MySono U6 Diagnostic Ultrasound System (K113381)
- The proprietary names of predicate devices (K130803 / K122583) have been changed to UGEO HM70A / UGEO H60 Diagnostic Ultrasound System from UGEO H70c / UGEO G60 Diagnostic Ultrasound System on FDA Databases.

# 4. Device Description:

The SONOACE R7 is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B mode, M mode, Color Doppler imaging, Power Doppler imaging(including Directional Power Doppler mode), PW/CWSpectral Doppler mode, Harmonic imaging, Tissue Doppler imaging, 3D imaging mode (real time 4D imaging mode) or as a combination of these modes. The SONOACE R7 also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The SONOACE R7 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

#### 5. Intended Uses:

The SONOACE R7 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal, Abdominal, Pediatric, Small Organs, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Cardiac Adult, Cardiac Pediatricand Peripheral vessel.

# 6. Technological Characteristics:

The SONOACE R7 is substantially equivalent with respect to safety, effectiveness, and functionality to the SONOACE R7 Diagnostic Ultrasound System (K112646) and ACCUVIX A30 Diagnostic Ultrasound System (K112339).

It is substantially equivalent with respect to safety, effectiveness, and functionality to the Bodymarker of SONOACE R7(K112646) in regards to the device with e-Motion Marker.

All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

These are described in detail in the technological characteristics comparison table as below.

<Technological Characteristics Comparison Table>

Feature / Characteristics Indication for Use - Fetal		1 1						
Indication for Use - Fetal	SONOACE R7	SONOACE R7 (X112646)	ACCUVIX A30 (K112339):	EKO 7 (K101455)	UGEO HM70A (K 130803)	UGEO 1160 (K122583)	MySono U6 (K113381)	UGEO PT60A (K132228)
- Fetal								
	٨	٨	٨	7	~>	٨	~>!	-7
- Abdominal	7	7	٨	٨	١,	٦	7	٨
- Pediatric	7	7	٨	7	۲	٨	7	
- Small Organ	7	7	7	7	۸ ا	٦	マ	7
- Neonatal Cephalic	7	7	7		7	۸ ا	٢	
- Adult Cephalic	7	7	7	٨	۴ -		>	٨
- Trans-rectal	7	7	7	7	٨	٨	7	
- Trans-vaginal	>	7	7	<b>^</b>	٨	٨	7	
- Musculo-skeletal	7	7	7	٢	7	7	マ	>
(Conventional)								-
<ul> <li>Musculo-skeletal</li> </ul>	>	>	マ	7	>	>	>	>
(Superficial)		al-Modes						
- Cardiac Adult	>	٨	۲,	٨	^		7	7
- Cardiac Pediatric	>	۲	. 7	٨	٨		7	7
- Peripheral vessel	>	٨	٨	٨	7	٨	7	7
Scanhead Types	† †			•				
- Linear Аттау	>	7	^	٦	· ~	7	>	^
- Curved Linear Array	٨	۲	٨	7	7	7	<b>&gt;</b>	7
- Endocavity	٦	٨	۶		7	٨	>	
- Phased Аттау	7	7	٨	۲	7	7	7	>
- Static Probes	>		7	۴	٨		7	
Scanhead Frequency	3		13	• •		•		
1.0 ~ 20.0 MHz	>	7	7	٨	٨	7	ァ	7
Modes of Operation	c		t.					
- B-mode	>	7	^	٨	١ ٠	マ	7	7
- M-mode	>	٨	٨	7	٨	٦	7	>
- Pulsed wave (PW) Doppler	7	١	7	٦	77	7	7	7
- Continuous wave (CW) Doppler	7		7	~	7		7	
- Color Doppler	7	7	7	7	٨	٨	>	7
- Power Amplitude	7	۶	٨	7	>	7	٨	>

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Characteristics   SONOACE R7   ACCUVIX A30   EKO7   UGEO H40    T. Harmonic   V   V   V   V   V   V    Harmonic   V   V   V   V   V   V    12.2 No.601.1   V   V   V   V   V    12.2 No.601.1   V   V   V   V   V   V    12.2 No.601.1   V   V   V    12.2 No.601.1   V   V   V    12.3 No.601.1   V   V   V    12.4 V   V   V    12.5 No.601.1   V		The subject		5	-	The prediente devices	Þ		-
	Feature / Characteristics	SONOACE R7	SONOACE R7 (K112646)	ACCUVIX A30 (K112339)	EKO 7 (K 101455)	UGEO HM70A (K130803) °	UGEO 1460 (K 122583)	MySono U6 (K113381)	UGEO PT60A (K132228)
	Doppler		1						
	- Tissue Harmonic	>	7	7	7	>	->	7	· ~
	Imaging			-		->	7	7	7
A A A A A A A A A A A A A A A A A A A	SD/4D imaging mode     Combined modes	> >	> >		7	- >	-	~ >	٨
	Safety & EMC Compliance			,					,
100-1	- IEC60601-1								-
22.2 No.601.1 22	- UL 60601-1	>	7	>	7	>	7	>	7
Compound   V   V   V   V   V   V   V   V   V	- CSA C22.2 No.601.1						i		
Conjour Display Standard	- IEC 60601-2-37	٨	٨	٦	7	7	>	>	>
Output Display Standard         V	- IEC 60601-1-2	>	7	٨	٨	٨	7	7	7
Variate   Vari	Acoustic Output Display St	andard	,.						1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Scan (Q Scan)   V   V   V   V   V   V   V   V   V	Track 3		7	٢	۲	٨	٠,	7	٨
Scan (Q Scan)   V   V   V   V   V   V   V   V   V	Patient Contact Materials								
Scan (Q Scan)	Tested to ISO 10993-1	7	>	7	7	٨	٨	٦.	١
Scan (Q Scan)         V         <	Functionality						. " !		4
Compound	- Quick Scan (Q Scan)	7	٨	١	ァ	7	7	7	٨
Equation   R	- Spatial Compound	7	7	7	7	7	>	7	7
(Dynamic MR	Imaging								
MT+(Auto IMT)   V	- SMDR (Dynamic MR Plus)	7	7	7	7	٨	7	7	7
Echo         V         V         V           ranic         V         V         V           can         V         V         V           aging         V         V         V           rition)         V         V         V           richard         V         V         V           richard         V         V         V           richard         V         V         V           Audering         V         V         V           V)         V         V         V	- Auto IMT+(Auto IMT)	7		7	7	٨		7	7
Echo         .	- Strain	>			٢				
mic   v   v   v   v   v   v   v   v   v	- Stress Echo	٨			>				
aging         V <th>- Panoramic</th> <th>7</th> <th>i</th> <th>٨</th> <th>مر</th> <th>7</th> <th></th> <th></th> <th></th>	- Panoramic	7	i	٨	مر	7			
pering when the Data when the	- Elastoscan	٨		7		7			
ition)  aging presentation  v v v inc/4D Cinc)  decring v v v v v v v v v v v v v v v v v v v	- 3D Imaging (Volume Data	~	7	7		7	7	7	
inc/4D Cinc)  v v v  inc/4D Cinc)  ndering  v v v  v  v  v  v  v  v  v  v  v  v  v	Acquisition)	,							
ndering V V V AMulti Planer V V	<ul> <li>3D Imaging presentation (3D Cine/4D Cine)</li> </ul>	7	7	·		7	7	7	
(c)	- 3D Rendering	,	, ,	7		7	7	~	
	Render)	>	<b>&gt;</b>	•	,				
	. 3D XI	٨	7	٨		>	>		

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	The subject		3 42 41 41 41 41	, , , , , , , , , , , , , , , , , , ,	The predicate devices		_	
Feature / Characteristics	SONOACE R7	SONOACE R7 (KÎ12646)	ACCUVIX A30 (K112339)	EKO 7 (K 101455)	UGEO HM70A: (K130803)	UGEO H60 (K 122583)	MySono U6 , (K113381)	UGEO PT60A (K132228)
MSV(Multi Slice View)								
Oblique View								
- 3D MagiCut	7	۲	۲		7	7	7	
- e-Motion Marker	7	ال	ربا^	راب	(اب	ح.[]	ν'n	۸,1,1

# 7. A brief discussion of the bench and non-clinical tests conducted on the subject device

The device has been evaluated for acoustic output, biocompatibility effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform to applicable medical device safety standards.

The SONOACE R7 and its application comply with voluntary standards as below:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2,EMC requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- ISO10993-1, Biocompatibility
- ISO14971, Application of risk management to medical devices

# Summary of Clinical Tests:

Not applicable. The subject of this submission, SONOACE R7, did not require clinical studies to support substantial equivalence.

#### 8. Conclusion

Intended uses and other key features are consistent with traditional clinical practices and FDA guidelines. The design, development and quality process of the manufacturer confirms with 21 CFR 820 and ISO 13485. The device is designed to conform to applicable medical device safety standards and compliance. Therefore, SAMSUNG MEDISON CO., LTD. considers the SONOACE R7to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

END of 510(K) Summary



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

December 27, 2013

SAMSUNG MEDISON CO., LTD C/O MARK JOB RESPONSIBLE THIRD PARTY OFFICIAL REGULATORY TECHNOLOGY SERVICES LLC 1394 25TH STREET NW BUFFALO MN 55313

Re: K133505

Trade/Device Name: SONOACE R7 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX Dated: November 13, 2013 Received: November 14, 2013

#### Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the SONOACE R7 Diagnostic Ultrasound System, as described in your premarket notification:

# Transducer Model Number

C2-5	C2-8	C4-9/10ED
ER4-9/10ED	EV4-9/10ED	L3-8
L5-12/50EP	LN5-12	HL5-12ED
P2-4AH	P3-7AC	3DC2-6
3D4-8ET	3D4-9ES	· C4-9
CF4-9	ER4-9	<b>EVN4-9</b>
L5-12/50	P2-4	PN2-4 SP3-8

3D4-8

3D4-9 CW2.0 **VN4-8** 

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <a href="http://www.fda.gov/MedicalDevices/Resourcesfor You/Industry/default.htm">http://www.fda.gov/MedicalDevices/Resourcesfor You/Industry/default.htm</a>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <a href="http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm">http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</a> for the CDRH's Office

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

of Surveillance and Biometrics/Division of Postmarket Surveillance.

Sincerely yours,

Janine M. Morris

Director

Division of Radiological Health Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

For

Enclosure

# DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

# Indications for lise

Form Approved: OMB No. 0910-0120 Expiration Date: December 31, 2013 See PRA Statement on last page.

lifulcations for osc	
510(k) Number (if known)	
K133505	
Device Name	
SONOACE R7 Diagnostic Ultrasound System	
Indications for Use (Describe)	
The SONOACE R7 Diagnostic Ultrasound System and transducers are	intended for disgnostic ultrasound imaging and fluid analysis
of the human body.	
The clinical applications include: Fetal, Abdominal, Pediatric, Small C vaginal, Muscular-Skeletal (Conventional, Superficial), Cardiac Adult	organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans- , Cardiac Pediatric and Peripheral vessel.
	·
	•
Type of Use (Select one or both, as applicable)	Committee Committee than 604 CER 504 Colored City
Prescription Use (Part 21 CFR 801 Subpart D)	Over-The-Counter Use (21 CFR 801 Subpart C)
PLEASE DO NOT WRITE BELOW THIS LINE - CO	ONTINUE ON A SEPARATE PAGE IF NEEDED.
FOR FDA U	SE ONLY
Concurrence of Center for Devices and Radiological Health (CDRH) (	Signature)
Michael D.	OHara

510(k) No.:

Device Name: SONOACE R7 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

+	Clinical Application					peration (*inc	cludes simultaneo	1
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 11
	Abdominal(See Note 10)	P	Р	P	P	P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	P	Р	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 12
	Small Organ (See Note 5)	P	Р	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 12
	Neonatal Cephalic	Р	Р	P		P	Note 1	Notes 2,8, 9
	Adult Cephalic	P	Р	P	P	P	Note I	Note 4, 7
	Trans-rectal	P	Р	P		P	Note 1	Note 2, 7, 8, 11
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 11
	Trans-urethral				1			<del></del>
	Trans-esoph. (non-Cardiac)				Ī	ľ		
•	Musculo-skel. (Convent.)	Р	Р	Р		Р	Note 1	Note 2, 5, 6, 7, 9, 12
	Musculo-skel. (Superfic.)	Р	Р	P		Р	Note 1	Note 2, 5, 6, 7, 9, 12
	Intra-luminal	1					ï	
	Other (spec.)							
	Cardiac Adult	P	P	P	P	P	Note I	Note 4, 7
Cardiac	Cardiac Pediatric	P	P	Р	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)						<u> </u>	
	Other (spec.)	Ī						
Peripheral	Peripheral vessel	Р	P	Р	P	P	Note 1	Note 2, 5, 6, 7, 8, 9, 12
Vessel	Other (spec.)					1		

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan

Note12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

510(k) No.:

Device Name: C2-5 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode of O	peration (*inclu	des simultaneous B	-mode)
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic						[	
	Fetal (See Note 3)	Р	P	Р		P	Note 1	Notes 2, 7, 8, 9
	Abdominal(See Note 10)	Р	Р	P		P	Note 1	Notes 2, 7, 8, 9
	Intra-operative (See Note 6)		[					
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	Р	P	P		P	Note 1	Notes 2, 7, 8, 9
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic						l I	
	Trans-rectal					ļ		
	Trans-vaginal							<del>"</del>
	Trans-urethral					ŀ		
	Trans-esoph. (non-Cardiac)							_
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult						Í	
Cardiac	Cardíac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							•

N= new indication; P= previously cleared byFDA K112646; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

510(k) No.:

Device Name: C2-8 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					<del></del>	des simultaneous B	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic	1 .						
	Fetal (See Note 3)	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Abdominal(See Note 10)	P	P	Р		P	Note 1	Notes 2, 7, 8, 9
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic				_			
& Other	Pediatric	P	P	P		P	Note I	Notes 2, 7, 8, 9
	Small Organ (See Note 5)						[	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal						Ī	
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal	1						
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral	Peripheral vessel						[	
Vessel	Other (spec.)						1	

N= new indication; P= previously cleared byFDA K112646; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11; ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)



510(k) No.:

Device Name: C4-9/10ED for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application			_	Mode of O	peration (*inclu	des simultaneous B-	mode)
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							-
·	Fetal (See Note 3)	P	Р	Þ		P	Note 1	Notes 2,8, 9
	Abdominal(See Note 10)	Р	P	P		P	Note I	Notes 2,8, 9
	Intra-operative (See Note 6)			1				
	Intra-operative (Neuro.)			T				-
Fetal Imaging	Laparoscopic							
& Other	Pediatric	P	Р	P		P	Note 1	Notes 2,8, 9
	Small Organ (See Note 5)	P	Р	P		P	Note 1	Notes 2,8, 9
	Neonatal Cephalic	Р	P	P		P	Note 1	Notes 2,8, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	1						
	Trans-urethral			1				
•	Trans-esoph. (non-Cardiac)				_			
	Musculo-skel. (Convent.)	Ì					Ì	
	Musculo-skel (Superfic.)							
	Intra-luminal	1						
	Other (spec.)	十						
	Cardiac Adult						1	·
Cardíac	Cardiac Pediatric	T		Ī			1	
	Trans-esophageal (Cardiac)						1	
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	Р		P	Note 1	Notes 2,8, 9
Vessel	Other (spec,)							

N= new indication; P= previously cleared byFDA K112646; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW,

Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging
Note 9: Panoramic imaging
Note 10: Includes Renal, Gynecology/Pelvis
Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

Section 1.3, page 5 Indications for Use



510(k) No.:

Device Name: ER4-9/10ED for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application						des simultaneous B-1	
General Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)	P	P	P		P	Note 1	Notes 2, 8
	Abdominal(See Note 10)	P	P	P		P	Note I	Notes 2, 8
	Intra-operative (See Note 6)							
	intra-operative (Neuro.)							
etal Imaging	Laparoscopic							
& Other	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic			1				
	Adult Cephalic							
	Trans-rectal	P	Р	Р		P	Note 1	Notes 2, 8
	Trans-vaginal	Р	Р	Р		P	Note 1	Notes 2, 8
	Trans-urethral	$\top$						
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)						1	
	Musculo-skel. (Superfic.)				ĺ			
	Intra-luminal	$\top$						
	Other (spec.)							
	Cardiac Adult	1						
Cardiac	Cardiac Pediatric	1						
	Trans-esophageal (Cardiac)	1						
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)			] ,				

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

# Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW,

Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH. Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

Section 1.3, page 6 Indications for Use

510(k) No.:,

Device Name: EV4-9/10ED for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application						des simultaneous B-1	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)	Þ	P	P		P	Note 1	Notes 2, 8
	Abdominal(See Note 10)	P	Р	P		P	Note I	Notes 2, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)	T						
Fetal Imaging	Laparoscopic						Ţ	
& Other	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic	$\top$						
	Adult Cephalic							
	Trans-rectal	P	. <b>P</b>	P		P	Note 1	Notes 2, 8
	Trans-vaginal	P	Р	Р		P	Note 1	Notes 2, 8
	Trans-urethral							- "
	Trans-esoph. (non-Cardiac)	$\top$		Ţ				
	Musculo-skel. (Convent.)					ļ		
	Musculo-skel. (Superfic.)	T						
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral	Peripheral vessel			1				
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDAK112646; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11; ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

Section 1.3, page 7 Indications for Use

510(k) No.:

Device Name: L3-8 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application						des simultaneous l	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)			j				
	Abdominal(See Note 10)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	N	N	N		N	Note I	Note 2, 5, 6, 7, 9, 12
	Small Organ (See Note 5)	N	N	N		N	Note I	Note 2, 5, 6, 7, 9, 12
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal			Î		Ĩ		
	Trans-urethral					"		
	Trans-esoph. (non-Cardiac)							
	Musculo-skel, (Convent.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 12
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 12
	Intra-luminal							
	Other (spec.)	T						· -
	Cardiac Adult	7						
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Cardiac)	1			ĺ			
	Other (spec.)							
Peripheral	Peripheral vessel	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 1:
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

510(k) No.:

Device Name: L5-12/50EP for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal (See Note 3)									
	Abdominal(See Note 10)			T .						
	Intra-operative (See Note 6)	Т								
	Intra-operative (Neuro.)	Т					Ĭ			
Fetal Imaging	Laparoscopic	T				[				
& Other	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 12		
	Small Organ (See Note 5)	Р	P	P		P	Note I	Note 2, 5, 6, 7, 9, 12		
	Neonatal Cephalic	Т						ĺ		
	Adult Cephalic	1		1			Ī			
	Trans-rectal	_								
	Trans-vaginal	1								
	Trans-urethral									
	Trans-esoph. (non-Cardiac)	$\neg$					<u> </u>			
	Musculo-skel. (Convent.)	P	Р	P		P	Note 1	Note 2, 5, 6, 7, 9, 1		
	Musculo-skel. (Superfic.)	Р	P	P	-	P	Note i	Note 2, 5, 6, 7, 9, 1		
	Intra-luminal	1								
	Other (spec.)	┱					<u></u>	<u> </u>		
	Cardiac Adult	7	1							
Cardiac	Cardiac Pediatric	1		1						
	Trans-esophageal (Cardiac)	1		1						
	Other (spec.)									
Peripheral	Peripheral vessel	Р	P	P		Р	Note 1	Note 2, 5, 6, 7, 9, 1		
Vessel	Other (spec.)	1		Ī						

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW,

Note 2: Includes infertility monitoring of follicle development

Note 4; Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

510(k) No.:

Device Name: LN5-12 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthalmic	Ophthalmic										
	Fetal (See Note 3)										
	Abdominal(See Note 10)										
	Intra-operative (See Note 6)					[					
	Intra-operative (Neuro.)				,	]					
Fetal Imaging	Laparoscopic	Ī									
& Other	Pediatric .	`P	P	P		P	Note I	Notes 2,5,6, 9, 11, 1			
	Small Organ (See Note 5)	P	P	Р		P	Note I	Notes 2,5,6, 9, 12			
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral			1		Ì					
	Trans-esoph. (non-Cardiac)										
	Musculo-skel. (Convent.)	Р	P	P		P	Note 1	Notes 2,5,6, 9, 12			
	Musculo-skel. (Superfic.)	Р	P	P		P	Note I	Notes 2,5,6, 9, 12			
	Intra-luminal			Ì							
	Other (spec.)										
	Cardiac Adult		Ì	Ī							
Cardiac	Cardiac Pediatric										
	Trans-esophageal (Cardiac)			Ĺ							
	Other (spec.)										
Peripheral	Peripheral vessel	P	P	P		P	Note 1	Notes 5,6, 9, 12			
Vessel	Other (spec.)			]							

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)

Note 1: B+M, B+C, B+PD, B+TD, B+PD

Note 1: B+M, B+C, B+PD, B+TD, B+PD

Note 1: B+C, B+PD, B+TD, B+PD

Note 2: B+C, B+PD, B+TD, B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

Section 1.3, page 10 Indications for Use

510(k) No.:

Device Name: HL5-12ED for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic	1								
	Fetal (See Note 3)									
	Abdominal(See Note 10)					-				
	Intra-operative (See Note 6)									
	Intra-operative (Neuro.)	$\neg$				_				
Fetal Imaging	Laparoscopic			1						
& Other	Pediatric	P	Р	P		P	Note 1	Note 2, 5, 6, 7, 9, 12		
	Small Organ (See Note 5)	P	Р	P		P	Note 1	Note 2, 5, 6, 7, 9, 12		
	Neonatal Cephalic	$\top$								
	Adult Cephalic							_		
	Trans-rectal				-	_				
	Trans-vaginal	1						·		
	Trans-urethral									
	Trans-esoph (non-Cardiac)	<b>T</b>								
	Musculo-skel. (Convent.)	Р	P	Р		P	Note I	Note 2, 5, 6, 7, 9, 12		
	Musculo-skel. (Superfic.)	þ	P	Р		P	Note 1	Note 2, 5, 6, 7, 9, 12		
	Intra-luminal			† i			-			
	Other (spec.)									
	Cardiac Adult	1								
Cardiac	Cardiac Pediatric									
	Trans-esophageal (Cardiac)			1				<u> </u>		
	Other (spec.)									
Peripheral ·	Peripheral vessel	P	Р	P		P	Note 1	Note 2, 5, 6, 7, 9, 12		
Vessel	Other (spec.)			1		<del>-</del>				

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

#### Additional Comments:

itional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

510(k) No.:

Device Name: P2-4AH for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode of O	peration (*inclu	des simultaneous B-	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)							
	Abdominal(See Note 10)	Р	P	P	Р	P	Note 1	Note 4, 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)			Γ				
etal Imaging	Laparoscopic							
& Other	Pediatric	T			l			
	Small Organ (See Note 5)							,
	Neonatal Cephalic					<u> </u>		
	Adult Cephalic	Р	Р	Р	P	P	Note i	Note 4, 7
	Trans-rectal							
	Trans-vaginal						1	•
	Trans-urethral		·				<u> </u>	
	Trans-esoph. (non-Cardiac)	1						<u>'</u>
	Musculo-skel. (Convent.)						Î	
	Musculo-skel. (Superfic.)						1	
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	Р	P	Р	P	P	Note 1	Note 4, 7
Cardiac	Cardiac Pediatric	P	P	P	P	Þ	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)			Ī				
	Other (spec.)					Ī		
Peripheral	Peripheral vessel							
Vessel	Other (spec.)		Ī					

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example; thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging
Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

510(k) No.:

Device Name: P3-7AC for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation (*includes simultaneous B-mode)  B M PWD CWD Color Combined* Other									
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthalmic	Ophthalmic										
•	Fetal (See Note 3)										
	Abdominal(See Note 10)	P	Р	Р	P	P	Note 1	Note 4, 7			
	Intra-operative (See Note 6)										
	Intra-operative (Neuro.)										
Fetal Imaging	Laparoscopic										
& Other	Pediatric		Ĭ								
	Small Organ (See Note 5)	1						_			
	Neonatal Cephalic	1									
	Adult Cephalic	P	Р	Р	P	P	Note 1	Note 4, 7			
	Trans-rectal						· · · · ·				
	Trans-vaginal						[				
	Trans-urethral			ĺ							
	Trans-esoph. (non-Cardiac)										
	Musculo-skel. (Convent.)					-					
	Musculo-skel. (Superfic.)										
	Intra-luminal										
	Other (spec.)										
	Cardine Adult	P	Р	Р	P	P	Note 1	Note 4, 7			
Cardiac	Cardiac Pediatric	P	P	Р	Р	P	Note 1	Note 4, 7			
	Trans-esophageal (Cardiac)										
	Other (spec.)										
Peripheral	Peripheral vessel										
Vessel	Other (spec.)					T -	!				

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW,

Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

510(k) No.:

Device Name: 3DC2-6 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application		Mode of Operation (*includes simultaneous B-mode)									
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)				
Ophthalmic	Ophthalmic											
	Fetal (See Note 3)	P	P	Р		P	Note 1	Note 2, 7, 8, 9				
	Abdominal(See Note 10)	P	Р	Р		P	Note I	Note 2, 7, 8, 9				
	Intra-operative (See Note 6)											
	Intra-operative (Neuro.)			i								
Fetal Imaging	Laparoscopic											
& Other	Pediatric	P	Р	P		P	Note 1	Note 2, 7, 8, 9				
	Small Organ (See Note 5)	$\top$										
	Neonatal Cephalic					ĺ						
	Adult Cephalic		Ì									
	Trans-rectal					1						
	Trans-vaginal						·					
	Trans-urethral						i					
	Trans-esoph. (non-Cardiac)			1		1						
	Musculo-skel. (Convent.)			†		<u> </u>						
	Musculo-skel. (Superfic.)							•				
	Intra-luminal	1					T - 1					
	Other (spec.)	1					· ·					
	Cardiac Adult	1		†	-							
Cardiac	Cardiac Pediatric											
	Trans-esophageal (Cardiac)	1					<del></del>					
	Other (spec.)	1										
Peripheral	Peripheral vessel	1				-						
Vessel	Other (spec.)											

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

510(k) No.:

Device Name: 3D4-8ET for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthalmic	Ophthalmic						,				
	Fetal (See Note 3)	P	P	P		P	Note I	Note 2, 7, 8, 9			
	Abdominal(See Note 10)	Р	P	P		Р	Note 1	Note 2, 7, 8, 9			
	Intra-operative (See Note 6)										
	Intra-operative (Neuro.)										
Fetal Imaging	Laparoscopic										
& Other	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8, 9			
	Small Organ (See Note 5)										
	Neonatal Cephalic						Ī				
	Adult Cephalic										
	Trans-rectal	1			,	T	Ï i				
	Trans-vaginal	1									
	Trans-urethral										
	Trans-esoph (non-Cardiac)										
	Musculo-skel. (Convent.)	1				<i>,</i>					
	Musculo-skel. (Superfic.)	1	1								
	Intra-luminal						ĺ	•			
	Other (spec.)	1					Ţ <u></u>				
	Cardiac Adult	$\top$									
Cardiac	Cardiac Pediatric					Ī	]	-			
	Trans-esophageal (Cardiac)										
	Other (spec.)							,			
Peripheral	Peripheral vessel										
Vessel	Other (spec.)	1									

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

# **Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW,

Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

Section 1.3, page 15 Indications for Use

510(k) No.:

Device Name: 3D4-9ES for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode of O	peration (*inclu	des simultaneous B-	
General (Track I only)	Specific (Tracks I & III)	В	. M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
-	Fetal (See Note 3)	P	P	P		P	Note I	Note 2, 7, 8
	Abdominal/See Note 10)	Р	P	P		P	Note i	Note 2, 7, 8
	Intra-operative (See Note 6)	$\neg \Box$						
	Intra-operative (Neuro.)	$\top$						
Fetal Imaging	Laparoscopic	$\Box$						•
& Other	Pediatric	1						
	Small Organ (See Note 5)	┰	Ì					
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	Р		P	Note 1	Note 2, 7, 8
	Trans-vaginal	Р	Р	P		P	Note 1	Note 2, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)					Ī		
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal	1						
	Other (spec.)							_
•	Cardiac Adult							
Cardiac	Cardiac Pediatric	1		1				
	Trans-esophageal (Cardiac)	$\neg \vdash$						
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)	$\top$						

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+D, B+TD, B+PD)

Note 1: B+M, B+C, B+D, B+TD, B+DD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+D, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

510(k) No.:

Device Name: C4-9for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec)	Other (Spec.)			
Ophthalmic	Ophthalmic										
	Fetal (See Note 3)	p	P	į,		ין	Note 1	Notes 8, 9			
	Abdominal(See Note 11)	þ	Р	Þ		P	Note 1	Notes 8, 9			
	Intra-operative (See Note to)										
	Intra-operative (Neuro )			1				· · · · · ·			
Fetal Imaging	Laparoscopie										
& Other	Pediatric	P	Ą	Р		P	Note t	Notes 8, 9			
	Small Organ (See Note 3)	Þ	P	P		P	Note 1	Notes 8, 9			
	Neonatal Cephalic	P	l,	P		P	Note 1	Notes 8, 9			
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral			1		Ì					
	Trans-esoph, (non-Cardiac)							-			
	Musculo-skel, (Convent.)										
	Musculo-skel (Supertic.)										
	Intra-luminal		1								
	Other (spec.)	1									
	Cardiac Adult	1									
Cardiac	Cardiac Pediatric	1									
	Trans-esophageal (Cardiac)	1		1			1				
	Other (spec.)	T		<u> </u>							
Peripheral	Peripheral vessel	P	Į,	P		P	Note 1	Notes 8, 9			
Vessel	Other (spec.)										

N new indication: P : previously cleared byFDA K113381; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note: L. B. M., B. PW, B+C, R+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2. Includes imaging for guidance of biopsy

Note 3. Includes infertdity monitoring of folliele development

Note 4. Color M-mode

Note 5. For example, thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6. Abdominal organs and peripheral vessel.

Note 7 Tissue Harmonic Imaging (1111)

Note 8: 3D imaging

Note 9 Panoramic imaging Note 10 Includes Renal, Gynecology Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

510(k) No.:

Device Name: CF4-9 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

_	Clinical Application				Mode of O	peration (*melu	des simultaneous B-i	
General (Track Lonly)	Specific (Tracks L& BI)	В	М	CWG	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic			{				
	Fetal (See Note 3)	P	þ	Ъ		l,	Note I	Notes 8, 6
	Abdominal/See Note 10)	₽	ľ	þ	_	Р	Note 1	Notes 8, 9
	Intra-operative (Sec Note 6)							
	Intra-operative (Neuro )				_			
Fetal Imaging	Laparoscopic							-
& Other	Pediatric	P	Þ	P		P	Note 1	Notes 8, 9
	Small Organ (See Vote 3)	Р	P	P		Þ	Note 1	Nows 8, 9
	Neonatal Cephalic	P	þ	Į,		Į,	Note I	Notes 8, 9
	Adult Cephalic							
	Trans-rectal	T						
	Trans-vaginal							
	Trans-methral							
	Trans-esoph. (non-Cardiac)	$\top$						
	Musculo-skel (Convent)							
	Musculo-skel (Supertic.)							<u> </u>
	Intra-luminal	1 -						
	Other (spec.)							
	Cardiae Adult							
Cardiac	Cardine Pediatrie							
	Trans-esophageal (Cardiae)			T				·
	Other (spec.)							
Peripheral	Peripheral vessel	Į,	P	P		p	Note I	Notes 8, 9
Vessel	Other (spec.)							

Nonew indication; Propreviously cleared byFDA K122583, Emadded under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note: U. B.-M., B.-PW, B.-C., B.-PD, B.-DPD, B.-TD, B.-CW, B.-C.-PW, B.-PD--PW, B.-DPD--PW, B.-TD--PW, B.-C.-M, B.-C.-CW, B.-PD--CW, Duallig, B.-C., B.-PD, B.-TD, B.-PD)

Note 2. Includes imaging for guidance of biopsy

Note 3. Includes infertility monitoring of folliele development

Note 4 Color M-mode

Note 5. For example, thyroid, parathyroid, breast, scrotum and penss in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7, Tissue Harmonic Imaging (THI)

Note 8 3D imaging

Note 9 Panoramic imaging Note 16 Includes Renal, Gyuccology Pelvis

Note 11. ElastoScan

Note 12 Spatial Compound Imaging

Prescription Use (Per 21 CFR 801.109)

Section 1.3, page 18 Indications for Use

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

510(k) No.:

Device Name: ER4-9 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation (*includes simultaneous B-mode)  B. M. DWD CWD Color Combined* Other									
General (Track Fonly)	Specific ( Fracks 1 & 111)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthalmic	Ophthalmic										
	Fetal (See Note 3)	þ	P	p		P	Note 1	Notes 2, 7, 8, 11			
	AbdominalrSee Note 109	þ	į,	P		Р	Note 1	Notes 2, 7, 8, 11			
	Intra-operative (See Vote 6)										
	Intra-operative (Neuro )										
etal lauging	Laparoscopie										
& Other	Pediatric										
	Small Organ (See Vote 5)										
	Neonatal Cephalic										
	Adult Cephalic										
	Timus-rectal	P	P	P		P	Note 1	Notes 2, 7, 8, 11			
	Trans-vaginal	Į,	P	P		þ	Note 1	Notes 2, 7, 8, 11			
	Trans-methral										
	Trans-esoph (non-Cardiac)										
	Musculo-skel (Convent)										
	Musculo-skel (Supertic)										
	Inua-luminal										
	Other (spec.)										
	Cardiae Adult		İ								
Cardiac	Cardiae Pediatric										
	Trans-esophageal (Cardiae)										
	Other (spec.)										
Peripheral	Peripheral vessel										
Vessel	Other (spec )	Ī									

Nonew indication: Propreviously cleared by FDA K122583; E= added under Appendix E

#### Additional Comments:

Cotor Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2. Includes imaging for guidance of biopsy

Note 3. Includes infertility maniforing of follicle development

Note 4 Color M-mode

Note 5. For example, thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6. Abdominal organs and peripheral vessel.

Note 7 Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9 Panoranne imaging Note 10 Includes Renal, Gynecology Pelvis

Note 11. ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

Section 1.3, page 19 Indications for Use

510(k) No.:

Device Name: EVN4-9 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application		Mode of Operation (*includes simultaneous B-mode)									
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Calor Doppler*	Combined* (Spec.)	Other (Spec.)				
Ophthalmic	Ophthalmic											
	Fetal (See Note 3)	P	p	t,		l,	Note 1	Notes 2, 7, 8				
	Abdominal/See Note 10)	P	Р	Ь		þ	Note 1	Notes 2, 7, 8				
	Intra-operative (See Note 1s)											
	Intra-operative (Neuro.)											
Fetal Imaging	Laparoscopic	Î										
& Other	Pediatric			,								
	Small Organ (See Note 3)	Ĭ			·		Í					
	Neonatal Cephalic											
	Adult Cephalie	T										
	Trans-rectal	P	b	Р		P	Note I	Notes 2, 7, 8				
	Trans-vaginal	į,	1,	Р		Р	Note 1	Notes 2, 7, 8				
	Trans-methral											
	Trans-esoph. (non-Cardiae)	1										
	Musculo-skel (Convent.)											
	Museulo-skel (Supertic.)											
	Intra-luminal	$\neg$		1								
	Other (spec.)											
	Cardiae Adult											
Cardiac	Cardiac Pediatric											
	Traus-esophageal (Cardiac)											
	Other (spec.)											
Peripheral	Peripheral vessel											
Vessel	Other (spec.)											

N= new indication; P= previously cleared by FDA K122583; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Disal(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7; Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: Includes Renal, Gyuecology/Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

510(k) No.:

Device Name: L5-12/50 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode of C	peration (*inclu	des simultaneous	B-mode)
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic	T -						
	Fetal (See Note 3)							
	Abdominal(See Note 10)	T					_	
	Intra-operative (See Note 6)	$\neg$						
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopie							
& Other	Pediatrie	N	N	N		N	Note I	Note 2, 5, 6, 7, 9, 12
	Small Organ (See Soile 5)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 11, 12
	Neonatal Cephalic						]	_
	Adult Cephalic		Ì					, _
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral	$\top$	1				1	
	Trans-esoph, (non-Cardiac)	1		1			1	
	Musculo-skel. (Convent.)	N	N	N		N	Note I	Note 2, 5, 6, 7, 9, 12
	Musculo-skel (Supertic.)	N	N	N		N	Note (	Note 2, 5, 6, 7, 9, 12
	Inm-luminal	$\top$	Î				<u> </u>	
	Other (spec.)	1		1				
-	Cardiac Adult							
Cardiac	Cardiac Pediatric	1						
·	Trans-esophageal (Cardiac)			Ī	1			
	Other (spec.)	1						
Peripheral	Peripheral vessel	N	N	N		Ň	Note 1	Note 2, 5, 6, 7, 9, 12
Vessel	Other (spec.)		Ī					

N= new indication: P= previously cleared by FDA; E= added under Appendix E

# Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note: 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of folliele development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotom and penis in adult, pediatric and neonatal patients

Note 6; Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging Note 9: Panoranne imaging Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

510(k) No.:

Device Name: P2-4 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application		_	Mo	de of Ope	ration (*includ	es simultaneous B-n	
General (Track Lonly)	Specific (Tracks I & HI)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic					•		
	Fetal (See Note 3)							-
	Abdominal/See Note 10)	P	P	P	þ	P	Note 1	Note 4, 7
	Intra-operative (See Note 6)							_
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	1						
& Other	Pediatric						]	
	Small Organ (See Note 5)							
	Neonatal Cephalic	1						
	Adult Cephalic	Þ	P	Р	Þ	P	Note I	Note 4, 7
	Trans-rectal							
	Trans-vaginal	1						
	Trans-urethral	1		<u> </u>			1	<u> </u>
	Trans-esoph. (non-Cardiac)	1						
	Musculo-skel. (Convent.)	1		Ì				
	Musculo-skel (Superfic.)	1	1					
	Intra-luminal							
	Other (spec.)		1 [					
	Cardiae Adult	₽	P	P	Р	р.	Note 1	Note 1, 7
Cardiac	Cardiac Pediatric	P	P	P	Р	P	Note I	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA K113381; E= added under Appendix E

#### Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler

  Note: 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dnal(B, B+C, B+PD, B+TD, B+PD)

  Note: 2: Includes imaging for guidance of biopsy

  Note: 3: Includes infertility monitoring of follicle development

- Note 4: Color M-mode
- Note 5: For example, thyroid, parethyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6; Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11; ElastoScan
- Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801,109)

510(k) No.:

Device Name: PN2-4 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application			Mo	de of Ope	ration (*includ	es simultaneous B-m	iode)
General (Track Loply)	Specific (Tracks I & III)	B	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Specj)
Ophthaimic	Ophthalmic							
_	Fetal (See Note 3)							
	Abdominal(See Note 11)	P	Ь	P	P	q	Note I	Note 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	,						•
& Other	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
•	Adult Cephalic	P	р	b	Þ	P	Note 1	Note 7
	Trans-rectal							
	Trans-vaginal			Ĭ	Ī			
	Trans-urethral							
	Trans-esoph. (non-Cardiac)					Ĭ		v ·
	Musculo-skel, (Convent.)				1			•
	Musculo-skel, (Superfie.)		1	ľ				
	Intra-luminal							
	Other (spec.)			I				
	Cardiae Adult	P	P	Þ	P	P	Note 1	Note 4, 7
Cardiae	Cardiac Pediatric	Ь	Р	P	þ	P	Note I	Note 4, 7
	Trans-esophageal (Cardiae)							
	Other (spec.)							
Peripheral	Peripheral vessel	Ī						
Vessel	Other (spec.)		Ī					

: N= new indication; P= previously cleared byFDA K132228; E= added under Appendix E

#### Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
  Note: 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+W, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW,
- Dual(B, B+C, B+PD, B+TD, B+PD)
- Note 2: Includes imaging for guidance of biopsy. Note 3: Includes infertility monitoring or folliele development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonie Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging Note 10: Includes Renal, Gynecology/Pelvis
  - Note 11: ElastoScan
  - Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

Section 1.3, page 23 Indications for Use

510(k) No.:

Device Name: SP3-8 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
General (Track Lonly)	Specific (Tracks J & III)	Ĭŝ	М	PWD	CWD	Culor Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthaimic	Ophthalmic										
	Fetal (See Note 3)										
	Abdominal(See Note 10)	Ν	N	N	N	N	Note 1	Note 4, 7			
	Intra-operative (See Note 6)										
	Intra-operative (Neuro )										
Fetal Imaging	Laparoscopic	1									
& Other	Pediatric	1						<u> </u>			
	Small Organ (See Note 3)	1		1							
	Neonatal Cephalic	1									
	Adult Cephalic	Ŋ	N	N	2	Z	Note I	Note 4, 7			
	Trans-rectal	7						<del></del>			
	Trans-vaginal										
•	Trans-methral						1				
	Trans-csoph. (non-Cardiac) +										
	Muscuto-skel. (Convent.)										
	Musculo-skel (Supertic.)										
•	Intra-luminal										
	Other (spec.)						Ī				
	Cardiac Adult	N	N	N	N	N'	Note 1	Note 4, 7			
Cardiac	Cardiac Pediatric	N	N	N	N	N	Note 1	Note 4, 7			
	Trans-esophageal (Cardiac)	1									
	Other (spec.)			İ							
Peripheral	Peripheral vessel										
Vessel	Other (spec.)										

N=new indication; P= previously cleared by FDA; E= added under Appendix E

#### Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
  Note: 1: R+M, B+PW, B+C, B+PD, R+DPD, R+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, R+TD+PW, R+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)

  Note: 1: R+M, B+PD, B+TD, B+TD, B+DPD, R+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, R+TD+PW, R+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes intertility monitoring of follicle development
- Note 4; Color M-mode
- Note 5: For example; thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging Note 16: Includes Renal, Gynecology/Pelvis
- Note 11: ElastoScan
- Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

Section 1.3, page 24 Indications for Use

510(k) No.:

Device Name: 3D4-8 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application		Mode of Operation (*includes simultaneous B-mode)									
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)				
Ophthalmic	Ophthalmic			. ]			_					
<u> </u>	Fetal (See Note 3)	ħ	þ	[ p		b	Note 1	Note 2, 7, 8, 9				
	Abdominal(See Note 10)	Р	Р	P		P	Note 1	Now 2, 7, 8, 9				
	Intra-operative (See Note 6)											
	Intra-operative (Neuro.)											
Fetal Imaging	Laparoscopic											
& Other	Pediatrie	l,	Ð	P		b.	Note 1	Note 2, 7, 8, 9				
	Small Organ (See Note 5)											
	Neonatal Cephalic											
	Adult Cephalic					_						
	Trans-rectal											
	Trans-vaginal											
	Trans-methral											
	Trans-esoph (non-Cardiac)				Ī							
	Musculo-skel, (Convent.)											
	Musculo-skel (Supertic.)											
	Intra-luminal											
	Other (spec.)											
<u> </u>	Cardiac Adult											
Cardiac	Cardiae Pediatrie											
	Trans-esophageal (Cardiac)											
	Other (spec.)											
Peripheral	Peripheral vessel											
Vessel	Other (spec.)											

N= new indication: P= previously cleared by FDA K112646; E= added under Appendix E

#### Additional Comments:

Cofor Doppler includes Power (Amplitude) Doppler

Note 1; B+M, B+PW, B+C, B+PD, B-DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B-PD+CW,

Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3; Includes intertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example, thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging Note 10: Includes Renal, Gynecology/Pelvis

Note 11; ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

510(k) No.:

Device Name: 3D4-9 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application						ides simultaneous B-	
General (Track Lonly)	Specific (Tracks I & III)	B	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic						<u> </u>	
	Fotal (See Note 3)	P	p	P		fr	Note 1	Note 2, 7, 8
	Abdominal(See Note 10)	μ	Ρ	P		P	Note 1	Note 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
etal Imaging	Laparoscopie	1						
& Other	Pediatric			<b>I</b>				
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Р	P	P		Р	Note I	Note 2, 7, 8
	Trans-vaginal	P	1,	Р		p	Note 1	Note 2, 7, 8
	Trans-methral							
	Trans-esoph (non-Cardiac)							
	Musculo-skel, (Convent.)	1						
	Musculo-skel (Superfic.)	1	Ī					
	Intra-luminal		1					
	Other (spec.)							
	Cardiae Adult							
Cardiac	Cardiae Pediatric	$\perp$						
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA K122583; E= added under Appendix E

#### Additional Comments:

intonar Commetts:

Color Doppler includes Power (Amplitude) Doppler

Note: 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes intertility monitoring of folliele development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9; Panoramic imaging

Note 16: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

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510(k) No.:

Device Name: VN4-8 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application		Mode of Operation (*includes simultaneous B-mode)									
General (Track Lonly)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)				
Ophthalmic	Ophthalmic											
	Fetal (See Note 3)	N.	N	И		N	Note I	Note 2, 7, 8, 9				
	Abdominal(See Note 10)	N	N	Ŋ		N	Note I	Note 2, 7, 8, 9				
	Intra-operative (See Note 6)					ľ						
	Intra-operative (Neuro )											
Fetal Imaging	Laparoscopic											
& Other	Pediatric :	N	N	N		N	Note 1	Note 2, 7, 8, 9				
	Small Organ (See Note 5)	1										
	Neonatal Cephalic	1										
	Adult Cephalic	1										
	Trans-rectal	T				ĺ		,				
	Trans-vaginal											
	Trans-urethral	1										
	Trans-esoph, (non-Cardiac)	1										
	Musculo-skel (Convent)	1										
	Musculo-skel (Superfic.)	T				Ī						
	Intra-luminal	1										
	Other (spec.)	1										
	Cardiac Adult											
Cardiac	Cardiae Pediatrie	1										
	Trans-esophageal (Cordiac)	Ī				_						
	Other (spec.) -											
Peripheral	Peripheral vessel											
Vessel	Other (spec.)											

N= new indication; P= previously cleared by FDA K130803; E= added under Appendix E

# Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW,

Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example; thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging Note 9: Panoramic imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoScan

Note 12: Spatial Compound Imaging

Concurrence of CDRH. Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

510(k) No.:

Device Name: CW2.0 for use with SONOACE R7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation (* includes simultaneous B-mode)									
General (Track Lonly)	Specifie (Tracks I & III)	В	М	PWD	CMD_	Color Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthalmic	Ophthalmic										
	Fotal (See Note 3)	$\top$									
	Abdominal(Sec Note 10)	7		<b>!</b>							
	Intra-operative (See Note 6)										
	Intra-operative (Neuro )										
Fetal Imaging	Euparoscopic										
& Other	Pediatric										
	Small Organ (New Note 5)		Γ	j							
	Neonatal Cephalic					<u> </u>	<u> </u>				
	Adult Cephalic				Ъ						
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral			1							
	Trans-esoph, (non-Cardiac)										
	Musculo-skel. (Convent.)							-			
	Musculo-skel (Supertic.)	$\Box$									
	Intra-luminal										
	Other (spec.)	$\Box$									
	Cardine Adult	Ι.			þ						
Cardiac	Cardiae Pediatrie				11						
	Trans-esophageal (Cardiac)			<u> </u>							
_	Other (spec.)							<u> </u>			
Peripheral	Peripheral vessel				P						
Vessel	Other (spec.)			I				_			

N=new indication: P= previously cleared by FDA K130803; E= added under Appendix E

#### Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note: 1: R+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD-PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PD+CW, Dual(B, B+C, B+PD, B+TD, B+PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes intertifity monitoring of follicle development

Note 4: Color M-mode

Note 5: For example; thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging Note 10: Includes Renal, Gynecology/Pelvis

Note 11: ElastoSean

Note 12: Spatial Compound Imaging

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801,109)

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